REMARKS

The applicants have studied the final Office Action dated July 9, 2001, and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 1-73 are pending, claims 1, 11, 35, 44, 47, 51-55 and 65 have been amended, and new claim 73 has been added. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

The applicants wish to thank the Examiner for her time in the October 23, 2001 telephonic interview with the undersigned. The discussions were helpful and are believed to have moved the case toward allowance. The applicants have amended the claims and have provided the following remarks in accordance with the discussions and agreement reached by the Examiner and the undersigned. The Examiner indicated that an additional search would be needed, but otherwise the Examiner agreed that the discussed amendments would overcome the cited prior art. Thus, the application should now be in condition for allowance. If the Examiner has any further questions or comments, the Examiner is requested to call the undersigned to advance the prosecution of the application in a follow up interview.

The remarks and comments made in the September 10, 2001 response to the final Office Action were not entered by the Examiner, and the Examiner indicated that the remarks would not be entered upon the filing of an appeal. Accordingly, the applicants respectfully request that the remarks be considered officially withdrawn and of no effect on the record of this case. The applicants also respectfully and expressly retract them. In addition, only the remarks and amendments in this response should be used in assessing the patentability of the now pending claims.

During the discussions, the Examiner requested that the claims be amended to more clearly define that the structure of the infusion device is for use in external applications rather than implanted applications. Claim 1 has been amended to recite "a housing adapted for use on

an exterior of the body." Thus, as discussed, claim 1 (as well as amended independent claims 11, 35, 44, 47, 51-55, 65 and new claim 73, which include this limitation) is now patentably distinguishable over the references cited in the July 10, 2001 final Office Action. Accordingly, the claims, as amended, now more clearly cover all external infusion devices, while avoiding devices that are completely implanted in the body of a patient. Also, the limitation on the housing should not be read as to exclude external infusion devices that utilize needles, tubes, catheters, cannulas, infusion sets, and/or the like to deliver a liquid to a body.

The Examiner also requested that claims be amended to more clearly define the indication device. Claim 1 has been amended to recite "an indication device, providing at least one of a visual indication, an audible indication or a tactile indication, to indicate when a command has been received and indicate when the command is being utilized to control the external infusion device such that the external infusion device is capable of being concealed from view on an individual when being remotely commanded" (emphasis added). Claims 11, 35 and 51 have been amended to recite similar language. Thus, claims 1, 11, 35 and 51 clearly recite that the indication device can provide at least one of either a visual, audible or tactile indication. However, it should be understood that this does not prevent embodiments of the external infusion device from using more than one of these indications at a time or from using or omitting the use of RF transmissions (or other transmissions as described in the specification) to a remote device to provide information in addition to or instead of the indication provided by the indication device. In addition, this does not preclude the use of an additional indication device on either the external infuse device or a remote device. Thus, as discussed, claim 1 (as well as amended independent claims 11, 35, 51, which include this limitation) is now patentably distinguishable over the references cited in the July 10, 2001 final Office Action. Accordingly, the claims, as amended, now more clearly cover indication devices that provide at least one of an audible, visual or tactile indication, while avoiding devices that use only RF transmissions and do not include an indication device.

Regarding independent claims 44, 47 and 65, there was no need to amend these claims for an indication device. Claim 44 recites a "vibration alarm," claim 47 recites an "audible alarm"

used in conjunction with and a "vibration alarm," and claim 65 recites a "vibration alarm," neither of which is disclosed, taught or suggested by the references cited in the July 10, 2001 final Office Action. Accordingly, claims 44, 47 and 65 are now in condition for allowance.

Regarding claims 52-55, no amendments to the indication device have been deemed necessary due to the inclusion of specific limitations directed to delivery modes that are not taught or discussed in any of the prior art cited by the Examiner or the applicants in their prior art statements. Claim 52 recites "at least two personal delivery patterns," claim 53 recites "at least two personal delivery patterns," claim 54 recites "at least two basal rate profiles" and claim 55 recites "at least two bolus types," none of which are taught or disclosed by the prior art. Thus, these claims are patentably distinguishable regardless of the type of indication provided.

New claim 73 recites "an indication device to indicate, independent of an RF transmission, when a command has been received and indicate when the command is being utilized to control the external infusion device such that the external infusion device is capable of being concealed from view on an individual when being remotely commanded" (emphasis added). Thus, claim73 recites that the indication device can provide an indication independent of any RF transmission that might be used to send information to another device. However, it should be understood that this does not prevent embodiments of the external infusion device from using or omitting the use of RF transmissions (or other transmissions as described in the specification) to a remote device to provide information in addition to or instead of the indication provided by the indication device. In addition, this does not preclude the use of an additional indication device on either the external infuse device or a remote device. Thus, as discussed, claim 73 is patentably distinguishable over the references cited in the July 10, 2001 final Office Action. Accordingly, the claim clearly covers indication devices that are independent of RF transmissions as the sole source of an indication.

During the interview, the Examiner also stated that she was unfamiliar with some of the various terms recited in the specification and used by those of ordinary skill in the art. The Examiner did confirm her agreement that these terms are known and understood by those of

ordinary skill in the art. However, the Examiner requested that the applicants provide a brief informational description of these terms to aid in her evaluation of the application and the prior art. The applicants have agreed to provide these descriptions to aid the Examiner. However, the applicants respectfully point out that these descriptions here are for illustrative purposes only, and should not be construed as limiting the scope of these terms to anything less (or its equivalents) than what is understood by those of ordinary skill in the art and/or that described in the specification. If the Examiner needs more information or additional clarification, the Examiner is requested to call the undersigned to discuss the Examiner's request. Absent any comments from the Examiner, the applicants understand that this is merely being provided to give her some information to aid the Examiner in a further search of the prior art.

Basal rate generally refers to a liquid administration rate needed to maintain a desired therapeutic level in a body under normal day to day conditions. The basal rate may be constant, vary over time, or be profiled in a customized manner. The basal rate may also change based upon a body's activity, sleep state, meals, health, stress, day of the week, location, being temporarily disconnected from the external infusion device, and/or the like.

Various versions of basal rates have been also described in the specification. For example, the claims recite "temporary basal rates" and "basal rate profiles."

Bolus generally refers to an amount of liquid provided to a body on demand. This is generally based upon a specific need to quickly elevate (and/or maintain) the therapeutic level in the body. The bolus may be provided over and above a basal rate, may be provided between basal rates and/or may be provided as the sole source of fluid. The bolus delivery may be delivered all at once, be provided over an extended period or be profiled to deliver in a customized manner. In many cases, the term bolus is modified to include a description of how the bolus is delivered over time. For instance, but without limitation, a square wave bolus is a bolus provided over a period of time, such that its appearance if plotted over a period of time would be in the shape of a square wave or pulse (i.e., a bolus is provided a constant rate for a discrete period of time). The bolus may be provided based upon a body's activity, sleep state,

meals, health, stress, day of the week, location, being temporarily disconnected from the external infusion device, and/or the like.

Various versions of a bolus have been also described in the specification. For example, the claims recite "extended bolus," "dual wave bolus," "profiled bolus," and/or "bolus types." In addition, other claims recite a bolus that is augmented with some type of indication, such as an "audio bolus" (bolus augmented with sound) and/or "vibration bolus" (bolus augmented with vibration).

A bolus estimator is utilized to provide a user with an estimate of an amount liquid in a bolus to be provided to the body. The bolus estimator is described as being in the external infusion device. The user would input various parameters into the external infusion device and then the external infusion device would calculate an estimate of the size of the bolus to be administered. The user can accept the estimated amount of the bolus or adjust it. In addition, but without limitation, the user may select how the bolus is delivered, such as all at once, profiled or a combination of both. The bolus estimator may be used to verify how much of a bolus is needed and to assist in training a user on how to determine the appropriate amount of fluid that should be provided in a bolus. In one example, but without limitation, the user may utilize anticipated carbohydrate intake, present glucose level and insulin sensitivity to determine how much insulin to deliver in a bolus.

To further aid the Examiner in her understanding of external infusion devices and diabetes, the applicants are submitting general marketing brochures, training manuals and books in an information disclosure statement. It is respectfully hope that this will be of assistance to the Examiner in her attempt to learn about diabetes and external infusion therapy in general.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at (818) 576-5313 should the Examiner believe a telephone interview would advance the prosecution of the application.

Respectfully submitted,

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